medications, to assess its impact on healthcare costs, and to deduce areas for further research. **METHODS:** A systematic literature search (1990–2004) using an exhaustive list of relevant search terms was performed to identify articles with qualitative and quantitative data on adherence with oral anti-diabetic agents (OAs) and insulin. Studies describing the economic impact of non-adherence, including impact of medication co-payment on level of adherence, were also reviewed. Electronic Medline® and PubMed® searches along with manual review of bibliographies were conducted in different phases for article retrieval. **RESULTS:** Adequate documentation of adherence and its economic impact was found in 51 studies. Most adherence studies were conducted on OAs. Thirty-seven retrospective studies showed that adherence to diabetes treatment ranged from 31% to 90%, mostly measured by medication possession ratio, with levels slightly lower among insulin patients. Results varied due to a diversity of applied methodologies, where definitions of compliance and persistence were calculated differently. Race, multiple dosing, mode of administration, and patients' behavioral factors were significantly associated with adherence levels. Economic consequences of poor adherence were identified from seven studies (five retrospective, one patient survey, and one longitudinal cohort study), which demonstrated an increase in hospitalizations, premature disability, and other adverse events resulting in higher healthcare costs. Increasing co-payments (7 retrospective studies) resulted in a decrease in taking medications leading to increased adverse events and subsequent healthcare costs. **CONCLUSIONS:** This review confirms the lack of adequate treatment adherence among patients with diabetes and illustrates the considerable economic impact. More sophisticated methods of determining medication adherence have the potential to more accurately estimate adherence rates. Research demonstrating adherence to insulin therapies, particularly insulin pens, and related economic consequences are lacking in the literature.

PDB33

THE RELATIONSHIP BETWEEN HEALTH RELATED QUALITY OF LIFE (HRQOL) AND PAIN RESPONSE IN PATIENTS WITH DIABETIC PERIPHERAL NEUROPATHIC PAIN (DPNP)

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OBJECTIVE: The objective of this study was to investigate the association between pain response and health-related quality of life (HRQoL) in patients with diabetic peripheral neuropathic pain (DPNP). **METHODS:** EQ-5D data was collected at baseline and endpoint in three large placebo controlled randomised trials which evaluated duloxetine treatment for DPNP over a 12-week horizon. Patients had a clinical diagnosis of pain due to bilateral peripheral neuropathy caused by diabetes, had a mean 24-hour average pain severity score ≥ 4 on the 11 point Likert scale ("0 = no pain" and "10 = pain as bad as you can imagine") and suffered from daily pain for at least 6 months. Treatment response was based on the level of change observed in the average pain severity score. Three levels of clinically meaningful pain response were defined: full response (≥50% change in average pain severity), partial response (30 to 49% change average pain severity), and no response (<30% change in average pain severity). Utility data at the trial endpoint were pooled and stratified into the corresponding pain response thresholds. **RESULTS:** Patients had pain and utility scores measured at baseline (n = 1139) and trial endpoints (n = 998) across the three randomised trials. The average pain score at baseline was 5.8 ± 1.5 with a corresponding utility score of 0.58 ± 0.26. At trial endpoint, patients in the no response to treatment category had lower utility scores (0.61 ± 0.24) compared to patients with either a partial response (0.70 ± 0.16) or full response (0.78 ± 0.16). In addition, a statistically significant negative correlation was found, indicating that increasing pain severity was strongly associated with lower HRQoL in DPNP patients. **CONCLUSION:** Pain response had a considerable impact on HRQoL in DPNP patients. In addition, pain severity scores were significantly associated with lower HRQoL.

PDB34

HEALTH-RELATED QUALITY OF LIFE IN PATIENTS WITH DIABETES MELLITUS—TYPE 1 AND TYPE 2

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OBJECTIVE: This study aimed to estimate the health-related quality of life (HRQL) utility score for patients with diabetes mellitus Type 1 and Type 2 on insulin and/or oral treatment using EQ-5D and to compare differences in HRQL for controlled and uncontrolled patients. **METHODS:** We surveyed 157 patients in a cross sectional study with treated Type 1 and Type 2 diabetes in Sweden (age range 20–65 years). Physicians recorded demographic and treatment information, including medications for diabetes. HRQL was measured using the EQ-5D questionnaire and was filled in by the patients at a physician visit. We evaluated the differences between groups (e.g. treatment regimes) using GLM-models. All statistical tests were performed at the 0.05-level of significance and were all two-sided. EQ-5D was linked to utility weights using an algorithm that converges ordinal ratings into a weighed composite score. **RESULTS:** The mean utility score for the entire sample was 0.81 (SD 0.21) with a median of 0.79 (min –0.18, max 1.00). Patients with Type 1 diabetes had a higher mean utility score (0.88) than patients with Type 2 diabetes. Patients treated with a mixed regimen of oral antidiabetics and insulin reported a lower utility score (0.76). However, differences between treatment groups were not significant at the 5% level ($p = 0.063$). No significant difference was estimated in the health utility score for patients with controlled diabetes according to Swedish guidelines in comparison to uncontrolled patients. Women had significantly lower EQ-5D utility score than men, 0.76 and 0.85 respectively ($p = 0.0217$). The utility score ranged from 0.92 in the youngest age group (age 20–45) to 0.78 to the oldest age group (age 61–65) ($p = 0.02$). **CONCLUSION:** Type 1 diabetes patients reported a higher HRQL than Type 2 diabetes patients. Women had significantly lower EQ-5D score than men.

PDB35

TOPIRAMATE TREATMENT IMPROVES QUALITY OF LIFE (QOL) AND NERVE FUNCTION IN PATIENTS WITH DIABETIC NEUROPATHY (DN)

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OBJECTIVE: To test the hypothesis that improved nerve function using the anti-epileptic/migraine drug topiramate would translate to better quality of life (QOL). **METHODS:** Twenty patients with diabetic peripheral neuropathy were consented and entered into a study on topiramate. The dosage for each patient was titrated over a six-week period from 25 mg per day to 50 mg twice a day. The patients remained on 100 mg a day for 12 weeks and then were tapered off the medication over an additional 4-week period. Each patient received quantitative sensory testing, electromyography, skin blood flow, skin biopsies, and neurological examinations before and after treatment with top-

iramate. Each patient also answered the Norfolk Quality of Life questionnaire for diabetic neuropathy (QOL-DN) before and after treatment. The QOL-DN questionnaire was used to assess the patients' perception of the effects of diabetic peripheral neuropathy on their quality of life. **RESULTS:** Total QOL: before = 27.76 ± 5.40, after = 17.29 ± 4.66 (P = 0.00028). Small fiber: before = 2.35 ± 0.77, after = 1.59 ± 0.68 (p = 0.149). ADLs: before = 1.83 ± 0.74, after = 1.22 ± 0.69 (p = 0.276). Symptom Score: before = 8.28 ± 1.24, after = 3.39 ± 0.69 (p = 0.00004). Autonomic Function: before = 1.06 ± 0.47, after = 1.00 ± 0.47 (p = 0.834). Large Fiber: before = 15.06 ± 3.30, after = 10.01 ± 2.79 (p = 0.0044). Topiramate significantly improved 3 of the 5 domains of QOL-DN. There was a significant correlation between the changes in QOL symptom score and proximal leg cold sensation (r = 0.459, p = 0.0448). In addition, the correlation between changes in QOL large fiber neuropathy score and objective changes in Total Neuropathy Score approached significance (r = 0.459, p = 0.0637). Thus, topiramate improves objective indices of nerve function and QOL. **CONCLUSIONS:** Nerve Function improvement and enhanced QOL can be used as a measure of response to therapy in clinical trials.

PDB36

EQ-5D IN TYPE 2 DIABETES: RELATIONSHIPS WITH QUALITY OF LIFE AND COMORBID CONDITIONS

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OBJECTIVES: While measures of quality of life (QoL) have been widely used in patients with Type 2 diabetes mellitus (T2DM), there is insufficient data on preference-weighted health status measures like the Euroqol EQ-5D. This study reports statistical relationships among the EQ-5D and QoL measures, and with comorbid conditions like obesity and depression. **METHODS:** Patients with T2DM at the outpatient clinics of a university hospital completed a mailed questionnaire which included the EQ-5D in addition to measures of generic health status (SF-12), diabetes-specific QoL (Audit of Diabetes Dependent Quality of Life-ADDQoL), and depressive symptoms (Center for Epidemiologic Studies Depression—CES-D). Patient reported data were merged with retrospective clinical data from electronic medical records. **RESULTS:** Usable response rate was 44.3% (n = 385). Average EQ-5D score was 0.71 (±0.21). Spearman correlations with the EQ-5D index were: SF PCS-12 (0.640), SF MCS-12 (0.534), CES-D (–0.578), ADDQoL (0.316). Average EQ-5D scores were significantly lower for patients on oral medications and insulin (0.65 ± 0.22) compared to those only on oral medications (0.76 ± 0.19) (p < 0.001), and in those with at least one diabetes-related complication (0.68 ± 0.22) compared to those without (0.74 ± 0.21) (p = 0.011). There were no significant differences on the basis of glycemic control levels obtained from patients' A1C. Approximately 86% of those reporting no anxiety and depression on the EQ-5D were classified as not having depressive symptoms on the CES-D (Chi Square = 144.6, p < 0.001; Somer's d = 0.66, p < 0.001). Nearly 73% of patients reporting moderate problems with mobility and usual activities each on the EQ-5D were clinically obese. Simple linear regression indicated that the SF PCS-12 and SF MCS-12 together explained 57% of the variance in EQ-5D scores. **CONCLUSIONS:** EQ-5D scores reflected deficits in health status on the basis of diabetes severity variables like treatment type and diabetes-related complications, as well as conditions co-morbid to T2DM like obesity and depression.

PDB37/DB1

PATIENT-REPORTED UTILITIES/DISUTILITIES ASSOCIATED WITH TREATMENTS FOR TYPE 2 DIABETES

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It has been shown in the literature that quality of life differs by anti-diabetic treatment. **OBJECTIVE:** This study investigates salient differences between exenatide and insulin—products that show similar efficacy for the treatment of type 2 diabetes. Namely, compared with insulin, exenatide is associated with weight loss rather than weight gain and a higher incidence of nausea early in treatment. The current study used standard gamble (SG) methodology to estimate the utility/disutility of these attributes. **METHODS:** Hypothetical diabetes-related health states (with variations in nausea and weight) were created based on clinical trial data and the input of clinical experts and patients. Patients in Scotland and England with type 2 diabetes rated these health states and their own current health state in SG interviews. Patients completed the EQ-5D, PGWB, and the Appraisal of Diabetes Symptoms (ADS). Construct validity and health state differences were examined with correlations, t-tests, and ANOVAs. **RESULTS:** A total of 129 patients (51 Scotland;78 England) completed standard gamble interviews. The mean utility of a health state at the patients' current weight without nausea was 0.89. Higher weight was associated with lower utility, and lower weight was associated with higher utility (e.g., 5% higher weight = 0.83; 3% higher weight = 0.85; 3% lower weight = 0.91; 5% lower weight = 0.92). Differences between health states that varied by weight were statistically significant (e.g., current weight vs. 3% higher and 3% lower; both p < 0.001). Health states with nausea were rated significantly lower than otherwise identical health states without nausea (p < 0.001). SG ratings of own health (mean = 0.87) demonstrated construct validity through significant correlations with patient-reported outcome measures. **CONCLUSIONS:** Findings suggest that patient standard gamble interviews are a feasible method for obtaining utilities for type 2 diabetes utilities/disutilities. The utilities obtained in this study would be appropriate for use in a cost-utility analysis of treatment for type 2 diabetes.

PDB38

A LITERATURE REVIEW OF TREATMENT SATISFACTION, ADHERENCE AND QOL INSTRUMENTS USED IN TYPE 1 AND 2 DIABETES

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OBJECTIVES: To describe and compare the domains and psychometric properties of selected instruments used in diabetes Type 1 and Type 2. **METHODS:** A systematic literature review of published studies was conducted using MEDLINE (1990–2005), EMBASE (1990–2005) and the Mapi Research Trust databases. Only studies describing the development or use of a referenced instrument assessing QOL, treatment satisfaction or adherence in patients with diabetes type 1 or 2 were reviewed. Articles including diabetic patients after transplantation were not included. **RESULTS:** Thirty instruments were identified: four for patients under Insulin treatment (type 1 & 2), two for type 2 diabetes, nine "diabetes generic" (type 1 and type 2 treated with Diet or tablets and/or insulin), five for devices, three for adherence, two for diabetic complications, two were batteries and three were generic questionnaires. Out of these only nine had good psychometric properties. Three of them were fully validated, including responsiveness: the DQLCTQ for insulin-